Saset (Chengdu) Inc.

Room 902 Block B, Plaza Asia-Pacific,
Kehua North Road 58#
Chengdu, Sichuan, China

APR 30 2009

510(k) Summary for the iMago c21 Diagnostic Ultrasound System

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92, and format of a 510(k) Summary.

1.0 Submitter Information

1.1 Submitter:

Saset (Chengdu) Inc.

Room 902 Block B, Plaza Asia-Pacific,

Kehua North Road 58#

Chengdu, Sichuan, China

1.2 Contact:

DONGCHYUAN LIU

General Manager

Phone: +86-28-85352318

Fax Number: +86-28-85350722

Email: yhyu@myassistor.com

1.3 Date prepared:

November 17 2008

2.0 Device Name

2.1 Common Name:

Diagnostic Ultrasound System

2.2 Proprietary Name:

iMago c21 Diagnostic Ultrasound System

2.3 Classification Name:

Name	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

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2.4 Classification:

Class II

2.5 Predicate Device:

Sonosite Hand-Carried Ultrasound system (k014116)

ES500 system (k020630)

2.6 Reason for submission:

New product.

3.0 Device Description

The iMago c21 Diagnostic Ultrasound System is highly mobile, software-controlled, totally digital processing and PC-based ultrasound imaging system capable of the following operating modes: B, M, Pulsed Doppler, Color Flow(including amplitude Doppler). The system can generate real-time compound images and harmonic images, as well as 3D images and Wide-Field-of-View images.
The system is designed for use in convex and linear scanning modes, and supports convex and linear array probes.

Frequency Ranges	2 - 7.5MHz
Transducer types	Convex array
	Linear array

The iMago c21 is designed to comply with the following standards:

- IEC60601-1:1990+A1:1993+A2:1995+A3:1996: Safety of medical electric equipment
- EN60601-1-2: 2001+A1:2006 Medical electrical equipment -Part 1-2: General requirements for safety-Collateral standard: Electromagnetic compatibility-Requirements and tests
- EN61000-3-2: 2006: Electromagnetic compatibility (EMC) Part 3-2: Limits for harmonic current emissions (equipment input current up to and including 16A phase)
- EN 61000-3-3: 1995+A1:2001+A2:2005: Electromagnetic compatibility (EMC) Part 3-2: Limitations of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current $\leqslant$16A per phase and subject to conditional connection.
- IEC60601-2-37:2001+A1:2005+A2:2005 Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
- NEMA UD 2-2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment

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4.0 Summary of Intended Uses

The iMago c21 medical ultrasound system is intended for visualization of ultrasound of internal organs, for medical diagnostic purposes only. The main applications are: General radiology, Abdominal (excluding fetal Doppler), Vascular, OB/GYN, Urology, Breast, Superficial Organ (Small Parts), Musculoskeletal, and Cardiology. Each application includes a set of exams, including the specific measurements, reports, pictograms, annotations and system presets. The detailed application is listed in the User Guide and all these applications must be operated by qualified and trained Physician or "Sonographer".

5.0 Comparison to Predicate Device

The iMago c21 Diagnostic Ultrasound System is substantially equivalent to the Sonosite Hand-Carried Ultrasound system which has been cleared by the k014116, the ES500 system from Ultrasonix Medical Corp with a 510(k) as k020630 with respect to intended use/ indications for use (except the ECG and fetal Doppler application), principles of operation and technological characteristics.

6.0 Technological Characteristics

The iMago c21 Diagnostic Ultrasound System has its unique technological characteristics. iMago c21 consists of probe, the frontend subsystem for beamforming, the mid-processor subsystem for baseband signal processing, the backend subsystem for image processing and a single board computer as the system platform supporting peripherals, like monitor, control panel, DVD/CDRW, etc..

iMago c21 is PC-based, i.e., using a single board computer (SBC) (or the industrial PC board) as the system platform under Microsoft Windows XP operating system. The input data will be the video image coming from the backend subsystem and the SBC will perform file management, measurement and report, image storage and display, and other image-based post-processing functions.

iMago c21 operates identically to the Ultrasonix Ergosonix 500 Ultrasound Diagnostic Scanner device in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as 2D or M-mode images. Doppler shift caused

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by blood flow is displayed as Color Flow, or as spectrum analysis. The modes of this device (2D, PW Doppler, Color Flow Mapping Doppler, Power Doppler) are the same as the Ultrasonix Ergosonix Ultrasound Diagnostic Scanner. Transducer patient contact materials are biocompatible.
The operating control of iMago c21 iMago c21 Diagnostic Ultrasound System is through a control panel which offers a way to change the system parameters from the devices of the keyboard, slider, button, rotary, toggle and track ball. The parameters are used to adjust image quality, such as TGC gain sliders, depth control, PRF, angling, focus, sample volume, and so on.

7.0 Safety Considerations

AS a track 1 ultrasound device, the iMago c21 Diagnostic Ultrasound System is designed to comply with the "Acoustic Output Measurement Standard for Diagnostic Ultrasound (2004)" published by the National Electrical Manufactures Association as UD-2.
With respect to limits on acoustic outputs, the iMago c21 System complies with the requirements of UD2, that the maximum MI and TI of the system and transducer do not exceed 1.0 in any operation modes. Besides, iMago c21 system is not intended to include fetal Doppler application.
With regard to general safety, the iMago c21 System is designed to comply with IEC 60601-1 (2001) Medical Electrical Equipment, Part 1: General Requirements for Safety, and IEC 60601-2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 2009

Mr. Dong Chyuan Liu
General Manager
Saset (Chengdu), Inc.
Room 902 Block B, Plaza Asia-Pacific
Chengdu, Sichuan 610041
CHINA

Re: K090059
Trade/Device Name: iMago c21 medical ultrasound system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX, and IYN
Dated: April 10, 2009
Received: April 14, 2009

Dear Mr. Dong Chyuan Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the iMago c21 medical ultrasound system, as described in your premarket notification:

Transducer Model Number

SA3C52B Convex Array
SA5L38B Linear Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Paul Hardy at (240) 276-3666.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use Statement

510(k) Number (if known): K090059

Device Name: iMago c21 medical ultrasound system

Indications for Use:

The iMago c21 medical ultrasound system is intended for visualization of internal organs and for medical diagnostic purposes only. The main applications are: General radiology, Abdominal (excluding fetal Doppler), Vascular, OB/GYN, Urology, Breast, Superficial Organ (Small Parts), Musculoskeletal, and Cardiology. Each application includes a set of exams, including the specific measurements, reports, pictograms, annotations and system presets.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090059

K090059

Diagnostic Ultrasound Indications for Use Format

System: iMago c21 Diagnostic Ultrasound System

Transducer: SA3C52B Convex Array Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1&3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging &Other	Fetal	N	N				BM	1,2
	Abdominal	N	N	N		N	BMDC	1,2
	Intra-operative(Specify)							
	Intra-operative(Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	BMDC	1,2
	Small Organ(Specify)	N	N	N		N	BMDC	1,2
	Neonatal Cephalic							
	Adult Cephalic	N	N	N		N	BMDC	1,2
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N	BMDC	1,2
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N		N	BMDC	1,2
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	BMDC	1,2
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging.

1: 3-D Imaging 2: Harmonic Imaging

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090059

K090059

Diagnostic Ultrasound Indications for Use Format

System: iMago c21 Diagnostic Ultrasound System

Transducer: SA5L38B Linear Array Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1&3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging &Other	Fetal	N	N				BM	1,2
	Abdominal	N	N	N		N	BMDC	1,2
	Intra-operative(Specify)							
	Intra-operative(Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	BMDC	1,2
	Small Organ(Specify)	N	N	N		N	BMDC	1,2
	Neonatal Cephalic							
	Adult Cephalic	N	N	N		N	BMDC	1,2
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N	BMDC	1,2
	Musculo-skeletal (Superficial)	N	N	N		N	BMDC	1,2
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N		N	BMDC	1,2
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	BMDC	1,2
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging.

1: 3-D Imaging 2: Harmonic Imaging

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Radiological Devices
510(k) Number K090059